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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,708	03/20/2002	Melton B. Affrime	AL01056K	2438

26853 7590 07/03/2003

COVINGTON & BURLING
ATTN: PATENT DOCKETING
1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	6

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,708	AFFRIME ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. Claims 8-58 are pending and presented for the examination.

A telephone call was made to Ms. Caplan, Doreen on June 24, 2003 to request an oral election to the above election requirement, but did not result in an election being made. The election requirement was considered and invited because the claimed species do not considered to be related to single inventive concept, PCT rule 13.1-2. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising allergic condition, inflammatory conditions, and, upon the election of the disclosed species, if allergic condition is elected, claims 15 is generic to a plurality of disclosed patentably distinct species comprising season allergic rhinitis, perennial allergic rhinitis, atopic dermatitis, urticaria or allergic asthma. Each condition has different pathology, etiology and treatment from another. Thus, they lack the same or corresponding special technical features, and the oral election is request to respond to the election requirement.

However, the examiner decided to withdraw the election requirement since the search required for each disclosed patentably distinct species is not considered to be burden. Therefore, election requirement is withdrawn and this office action supercedes any office action or attempt prior to this.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 8-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating allergic and inflammation conditions(e.g. allergic rhinitis, allergic asthma, urticaria, atopic dermatitis) of the skin or airway passages in a human, does not reasonably provide enablement for preventing said conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 USC 112, first paragraph, the following factors must be considered(In re Wands, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

1) Nature of invention

2) State of prior art

3) Level of ordinary skill in the art

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor

6) Existence of working examples

7) Breadth of claims

8)Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a method for preventing an allergic and inflammatory conditions of the skin or airway passages in a human using an effective amount of desloratadine wherein the bioavailability of desloratadine is not affected by food.

2) State of the prior art

The references do not indicate that desloratadine or non-sedating antihistamine(e.g. loratadine) may be useful for treating the said disorders or conditions. Applicant cites references on page 1 that pertain to the treating allergic reactions.

3) Level of ordinary skill in the art

The level of ordinary skill in the art is high. The pathologies and etiologies for allergic or inflammatory conditions are not completely known. There are some biological pathways elucidated and known to the public, but not all the possible biological pathways or causative factors are completely discovered and known. For example, cytokine is also responsible for allergic and inflammatory reactions. However, applicant's specification does not enable the public to recognize and prevent all the possible causes and to block all the biological pathways that result in allergic and inflammation conditions.

4) Level of predictability in the art

The arts pertaining to the prevention of said allergic and inflammatory conditions remains unpredictable because the tests and assays require various experimental procedures and without guidance, there is little predictability in performing the claimed invention.

5) Amount of direction and guidance provided by the inventor

Applicant's limited guidance does not enable to public to administer the claimed invention for the prevention of the said conditions. For instance, Applicant states that desloratadine shows histamine inhibitory effect in vivo studies. However, it is known to the public that histamine is not the only material to cause allergic and inflammatory reactions. Thus, there is no directional guidance for prevention of said conditions. Major portion of applicant's specification discloses the treatment but not for the prevention.

6) Existence of working examples

Applicant fails to provide any working examples to prove the claimed invention is enabled.

7) Breadth of claims

The claims are extremely broad.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to prove the preventing said conditions.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed

process without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975 .

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 8-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberg et al (US 5,595,997).

US'997 teaches a method of treating allergic reactions such as allergic rhinitis, allergic asthma, urticaria, dermatitis(dermal irritations) using a therapeutically effective amount of desloratadine(DCL),see columns 7-8.

The therapeutically effective daily dose range of DCL for the said treatment is about 0.1 to 10mg per day, preferably 0.1 to 5mg, see column 8, lines 30-42.

US'997 further teaches a pharmaceutical dosage forms such as tablet, aqueous or non-aqueous liquid, liquid emulsions, etc, see column 9, lines 52-67. DCL and it's use in said treatment appears to be conventional knowledge wherein the claimed treatment (e.g. allergic rhinitis, allergic asthma, urticaria, atopic dermatitis) well known and documented in the art, evidenced by numerous documents.

Food effects is inherent feature where DCL administration for the said treatment will be naturally avoiding the food effect and steady bioavailability will be obtained regardless knowing food effect or not, fed or fasted treatment.

The claimed element (i.e. food effects) is considered to be new discovery of its pharmacokinetic characteristics if it never been known, however, it is not considered to be a patentably subject matter.

The new discovery of the food effects assures the users with better confidence and convenience. In fact, the food effect has been known and the information is available in the art(see PTO-892, for example, Nomeir's teaching-1996) However, it does not make the claimed subject patentably distinguished from treatment taught by the prior art of the record. The allegation this examiner presented can be evidenced by comparison of the effective dosage used in the said treatment (instant application *vs.* prior art of the record). Thus all the claimed subject matter is not patentably distinct and all the pending claims are properly included in this rejection.

Conclusion

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications

and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
June 27, 2003
Art unit 1614